

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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In re Patent Application of:  
John S. Haurum et al.

Application No.: 10/540,227

Confirmation No.: 6313

Filed: March 6, 2006

Art Unit: 1639

For: METHOD FOR MANUFACTURING  
RECOMBINANT POLYCLONAL PROTEINS

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Examiner: T. D. Wessendorf

**RESPONSE TO RESTRICTION REQUIREMENT**

MS Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Claims 1-40 and 48-52 are pending in the instant application and are subject to restriction.

The Office Action, on page 2, requires restriction to one of the following groups under 35 U.S.C. §121:

- I. Claims 1-20, drawn to a method for generating a collection of cells suitable as a recombinant polyclonal manufacturing cell line, classified in class 435, subclass 4+.
- II. Claims 21-31, drawn to a method for the manufacture of a polyclonal protein, wherein said polyclonal protein comprises distinct members that bind a particular antigen, classified in class 530, subclass 350+.
- III. Claims 32-36, drawn to a recombinant polyclonal manufacturing cell line comprising a collection of cells transfected with a library of variant nucleic acid sequences, classified in class 435, subclass 6+.
- IV. Claims 37-40, drawn to a library of vectors for site-specific integration comprising a population of naturally occurring variant nucleic acid sequences, classified in class 536, subclass 32.1+.

- V. Claims 48-52, drawn to a collection of cells comprising a library of variant nucleic acid sequences, where each of said nucleic acid sequences encodes a distinct member of a polyclonal protein comprising distinct members that bind a particular antigen, classified in class 435, subclass 4+.

In response to the restriction requirement set forth in the Office Action mailed April 2, 2008, Applicants hereby provisionally elect Group I, claims 1-20. In addition, the Examiner requires election of a species of screening procedure from among those listed in claim 10, a species of mammalian cell line from among those listed in claim 20, and a polyclonal antibody or antibody fragment from among those listed in claims 3 and 4. In response, Applicants elect the following species: ELISA from among those screening procedures recited at claim 10, the CHO cell line from among those mammalian cell lines recited at claim 20, and the T-cell receptor polyclonal antibody. Applicants respectfully traverse the restriction requirement.

Applicants assert that the subject matter of these groups represent different embodiments of a single inventive concept for which a single patent should issue. The pending claims represent an intricate web of knowledge, continuity of effort, and consequences of a single invention, which merit examination of all of these claims in a single application. More particularly, aspecial technical features under Rule 13.2 PCT link all of the claims. This single, searchable, unifying aspect comprises the discovery that a collection of cells may be used to express polyclonal proteins, each of which binds a particular antigen. Moreover, each distinct member of these polyclonal proteins is expressed using an expression construct that has been integrated into the genome of each cell at a specific integration site.

In addition, Applicants submit that a sufficient search and examination with respect to the subject matter of all claims can be made without serious burden. As the M.P.E.P. states:

If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions. M.P.E.P. § 803 (8th ed., Rev. No. 2, May 2004).

That is, even if the above-enumerated groups of claims are drawn to distinct inventions, the Examiner must still examine the entire application on the merits because doing so will not result in a serious burden. This is especially true given the robust and extensive computerized search engines and databases at the Examiner's disposal. Moreover, Applicants note that the entire application was searched by the international Examiner, and that the International Search Report was provided to the U.S. Patent and Trademark Office at the time of

filing. Accordingly, it is respectfully requested that the restriction requirement be reconsidered and the elected claims of Group I be rejoined with those of Groups II-V so that each of claims 1-40 and 48-52 may be presently examined.

Dated: June 2, 2008

Respectfully submitted,

By 

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